Vanda Pharmaceuticals announces the publication in PLOS One of an article titled "Melatonin agonist tasimelteon (HETLIOZ®) improves sleep in patients with primary insomnia: A multicenter, randomized, double-blind, placebo-controlled trial"

September 25, 2025

WASHINGTON, Sept. 25, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced the publication of an article titled "Melatonin agonist tasimelteon (HETLIOZ®) improves sleep in patients with primary insomnia: A multicenter, randomized, double-blind, placebo-controlled trial" in PLOS One, a leading open-access journal.[1]

In the study, published on September 24, 2025 in PLOS One, HETLIOZ® met its primary endpoint, demonstrating a mean improvement in latency to persistent sleep (LPS) from baseline to the average of Nights 1 and 8 of 44.9 minutes (20 mg) and 46.3 minutes (50 mg) versus 28.2 minutes (placebo) ($p < 0.001$). Improvements in LPS persisted through the follow-up time points (Nights 22 and 29, $p < 0.01$). Additionally, HETLIOZ® use was not associated with cognitive or mood changes, and neither rebound nor withdrawal effects were observed after discontinuation.[1] For access to the full study, visit DOI: https://doi.org/10.1371/journal.pone.0332366.

Insomnia, which affects over 10% of the American population and causes significant morbidity and next day consequences, remains a significant health problem for Americans.[2,3]

HETLIOZ® is a melatonin receptor agonist and circadian regulator that is approved for the treatment of Non-24-Hour Sleep-Wake Disorder in adults and for the treatment of nighttime sleep disturbances in adults and children with Smith-Magenis Syndrome. Vanda is continuing to pursue U.S. Food and Drug Administation (FDA) approval for HETLIOZ® in the treatment of insomnia and Jet Lag Disorder and is continuing to develop HETLIOZ® for the treatment of several other sleep disorders including Delayed Sleep Phase Disorder (DSPD) and pediatric insomnia.

References:

1. Synnott NC, Polymeropoulos CM, Xiao C, Birznieks G, Polymeropoulos MH (2025) Melatonin agonist tasimelteon (HETLIOZ®) improves sleep in patients with primary insomnia: A multicenter, randomized, double-blind, placebo-controlled trial. PLOS ONE 20(9): e0332366. https://doi.org/10.1371/journal.pone.0332366
2. Institute of Medicine (US) Committee on Sleep Medicine and Research. Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem. Colten HR, Altevogt BM, editors. Washington (DC): National Academies Press (US). 2006.
3. Roth T. Insomnia: definition, prevalence, etiology, and consequences. J Clin Sleep Med. 2007;3(5 Suppl):S7-10. pmid:17824495

About Vanda Pharmaceuticals Inc.

Vanda is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com and follow us on X @vandapharma.

About HETLIOZ®

For full U.S. Prescribing Information for HETLIOZ®, including indication and Important Safety Information, visit www.hetlioz.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding Vanda's pursuit of FDA approval of HETLIOZ® in the treatment of insomnia and Jet Lag Disorder and Vanda's clinical development plans for HETLIOZ® in the treatment of other sleep disorders, including DSPD and pediatric insomnia, are "forward-looking statements" under the securities laws. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward-looking statements are based upon current expectations and assumptions that involve risks, changes in circumstances and uncertainties. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include, among others, Vanda's ability to receive a hearing with the FDA regarding the Company's supplemental New Drug Application (sNDA) for HETLIOZ® in the treatment of insomnia and Vanda's ability to obtain FDA approval thereof, the outcome of the FDA's further review of the supplemental New Drug Application (sNDA) for HETLIOZ® in the treatment of Jet Lag Disorder, and Vanda's ability to complete the clinical development and obtain FDA approval of HETLIOZ® for the treatment of DSPD, pediatric insomnia and other sleep disorders. Therefore, no assurance can be given that the results or developments anticipated by Vanda will be realized, or even if substantially realized, that they will have the expected consequences to, or effects on, Vanda. Forward-looking statements in this press release should be evaluated together with the various risks and uncertainties that affect Vanda's business and market, particularly those identified in the "Cautionary Note Regarding Forward-Looking Statements", "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's most recent Annual Report on Form 10-K, as updated by Vanda's subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov.

All written and verbal forward-looking statements attributable to Vanda or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Vanda cautions investors not to rely too heavily on the forward-looking statements Vanda makes or that are made on its behalf. The information in this press release is provided only as of the date of this press release, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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